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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,452	03/18/2005	Kyoichiro Iida	00005.001256.	4898
5514 7590 G30002009 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA			EXAMINER	
			QAZI, SABIHA NAIM	
NEW YORK, NY 10112			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/528,452 IIDA ET AL. Office Action Summary Examiner Art Unit Sabiha Qazi 1612 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-37 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-37 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/S5/08)
Paper No(s)/Mail Date \_\_\_\_\_\_.

Attachment(s)

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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### DETAILED ACTION

Claims 1-37 are pending, preliminary amendments filed on 3/18/2005 are entered.

### Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-28 are drawn to [1,3,4]triazolo[1,5c]pyrimidine compounds of formula (I) when R3 represents formula (A3).

Group II, claims 1-28 are drawn to compounds of formula (I) when R3 represents formula (B1).

Group III, claims 1-28 are drawn to compounds of formula (I) when R3 represents formula (C3).

Group IV, claims 1-28 are drawn to compounds of formula (I) when R3 represents formula (E1).

Group V, claims 1-28 are drawn to compounds of formula (I) when R3 represents formula (F1).

Group VI, claims 1-28 are drawn to compounds of formula (I) when R3 represents formula (A4).

Group VII, claims 1-28 are drawn to compounds of formula (I) when R3 represents formula (A3).

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Group VIII, claims 1-28 are drawn to compounds when R3 is other than (A3), (B1), (C3), (E1), (F1), (A4), (A3).

Group IX, claims 26-37 are drawn to method of using the compounds.

The inventions listed as Groups I to VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The compounds and process of making as claimed in groups I to VIII contain different core with different chemical structures and therefore lack unity of invention. Each formula includes large number of compounds.

The compounds represented by general formula (I) in claim 1 share the structural feature of a 2-(aromatic)-5- (secondary amine)-[1,2,4] triazolo [1,5-c]pyrimidine derivatives of formula (I) is a partial structure and is not novel because they disclosed in the references cited in the specification. Therefore, no technical relationship involving a "special technical feature" can be established among the compounds containing triazolo-pyrimidine group. Therefore, the invention as claimed cannot be considered to be so linked as to form a single general inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1

Annex B of the PCT Administrative Instructions contains the following guidance with respect to Markush group claims when determining Unity of Invention:

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- (f)(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:
- (A) all alternatives have a common property or activity, and
- (B) (1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or
- (B) (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.
- (ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.
- (iii) In paragraph (f)(i)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

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(iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention

The examiner in making a Lack of Unity holding has divided the Markush Group into a number of different Groups based on lack of a special technical feature defined as lacking a significant structural element which defines over the art. The examiner has held that the significant structural element, the steroid structure, does not define over the art.

Due to complexity of the invention no call was made to request the election

Applicant is required, in reply to this action, to elect a single species from the elected group for the search purposes to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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2. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. Applicant is requested to elect a single species from the elected group for the search purposes.

#### Restriction to Common Core

This application contains claims directed to patentably distinct inventions (NOT species) as follows: each of the specifically claimed core compounds encompassed by claimed compounds for example heteroatoms is selected from O, and N as defined for D in formula (I), see also the reasons cited above. Furthermore, claims are drawn to different compounds having different core because of different chemical structures, which lack unity of invention as the compounds have no substantial structural similarities although they have a common utility. In re Harnisch, 631 F.2d 716, 206 USPQ 300(CCPA 1980); Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Thus, Applicant is advised that a reply to this requirement must include an identification of the invention and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

In summary, applicant should elect ONE COMMON CORE. Election of Species of Substituents Art Unit: 1612

Applicant should note that selection of ONE COMMON CORE is for RESTRICTION purposes. Once a common core has been elected, applicant will be further required to elect one specific chemical compound having that core.

Again, applicant should note that selection of this specific compound is an election of species, not a restriction. Accordingly, should a particular elected compound be found free of prior art, the search will be extended to additional non-elected substituents on said core.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. <u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim

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will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

## Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/ Primary Examiner, Art Unit 1612